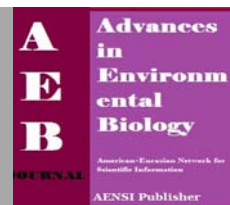




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The survey of the effect of ginger extract on gastric residual volume in mechanically ventilated patients hospitalized in the Intensive Care Units

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ABSTRACT

Background and purpose: Delayed gastric emptying in mechanically ventilated patients is common. According to evidences, Ginger can accelerate gastric emptying. This study aimed to determine the effect of ginger extract on gastric residual volume of patients admitted to the Intensive Care Unit. **Materials and Methods:** In this double-blind randomized controlled clinical trial with *before* and *after* schematization, 24 mechanically ventilated patients hospitalized in ICUs were divided into two groups, intervention group (12 patients) and control group (n = 12) after matching for sex and severity of disease. After 48 hours of feeding with a standard gavage solution, the intervention group received 120mg of ginger extract in 4 days and the control group received 5 ml water as placebo in 4 days. The mean residual volume was recorded in the fifth and sixth days were (24.58±16.81) in intervention group and (108.33±15.09) in control group that according to the Independent T-test showed a significant difference (P <0.0001). **Discussion and Conclusion:** The result of this study showed that ginger extract reduces gastric residual volume in mechanically ventilated patients hospitalized in intensive care units compared with placebo.

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INTRODUCTION

Nutritional support is the inherent part of a standard care of patients admitted to the Intensive Care Units [1]. Appropriate nutrition reduces mortality and pathogenesis of severely ill patients [2]. GI diet method is the preferred nutrition method in patients admitted to Intensive Care Units and its benefits are reduction of septic shock, organ failure, and length of hospital stay [1]. Patients' ulcers heal faster and the catabolic response to injury reduces by giving appropriate nutritional supports, also structure and function of the digestive system will be improved and length of the Intensive Care Unit stay and complication rates will be reduced and costs of hospital admission will be saved [3]. Several studies indicate 43-63% hospitalized patients in Intensive Care Units, also it is reported that only 42-76 percents of the patients hospitalized in Intensive Care Units receive the required calories [4]. More than 40% of patients in Intensive Care Unit are suffering from malnutrition and malnutrition lead to increased mortality and pathogenesis, immune system and ventilation condition disorders and weakening respiratory muscles [5]. Delayed gastric emptying mainly causes gastric intolerance to gavages in 30 to 51% of the patients and increase in gastric residual volume, vomiting, increase in the risk of aspiration and the length of stay in hospital [4,6] Delayed gastric emptying also lead to increase in gastric residual volume in 39% of patients [7].

On the other hand, 39% of patients in the Intensive Care Unit require mechanical ventilation [8]. although mechanical ventilation is a life-saving treatment and one of the basis of treatment [7,9], but has several side effects on different systems such as digestive system and lead to gastrointestinal function changes and disorders [7,10]. Delayed gastric emptying and gastrointestinal motility disorder is the most well known gastrointestinal

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problem in the severely ill patients undergoing mechanical ventilation. Several methods can be used for assessing the nutritional tolerance and rectifying delayed gastric emptying such as measuring the residual volume of the stomach, listening to intestinal sounds and abdominal radiography. Some of the treatment to cure delayed gastric emptying is feeding through a tube into the jejunum, using the feeding method of Beh Luas, or using gastrointestinal motility enhancing drugs and Herbal remedies [11-13].

Recently greater attention paid to use of alternative therapies such as herbal remedies for digestive problems [14]. Herbal remedies are natural plants and have fewer side effects so that they could be appropriate alternatives to chemical medications with low efficiency and high adverse effects [15]. One of the plants that is used and has highly medication uses is ginger [16]. Ginger is obtained from the rhizome of *Zingiber* and is used in food of people in Asia and the Far East since thousands years ago. Using the rhizome for digestive problems such as indigestion, anti-spasms, nausea and vomiting has been known to be safe. Ginger can accelerate the gastric emptying [8]. Since ginger directly affects the gastrointestinal tract, it prevents the side effects of other anti-nausea drugs on the central nervous system [17]. Few studies have been done on the effect of ginger extract on the gastric residual volume in gastrointestinal tract in patients fed with tubes therefore this study has been done with the purpose of determining the effect of ginger extract on gastric residual volume in mechanically ventilated patients in the Intensive Care Unit.

MATERIALS AND METHODS

This is a double-blind randomized controlled clinical trial with *before* and *after* schematization, which is performed on two groups of 12 patients, (intervention and control group), under mechanical ventilation hospitalized in 3 Intensive Care Units in Gorgan's Educational and Medical center, 5Azar Hospital in 1390. Accessible non-probability sampling with randomly assigning was used to intervention and control groups. Inclusion criteria were age 18-65 years old. Mechanically ventilated patients, feeding through the gastric catheter, internal diseases and exclusion criteria were people. Using gastrointestinal motility enhancing drugs during the past two weeks or during the study, patients are with gallstones, pregnancy, lactation, active bleeding, cerebral hemorrhage, taking corticosteroid, malignancies, hypoglycemia, hyperglycemia or diabetes, ulcers of the digestion system, food allergies, feeding with duodenum catheter and passing more than 48 hours duration after beginning gastrointestinal feeding. In the first 48 hours, both group's intervention and control were given the nutrition of same and standard formulation so that the study groups would be the same in nutrition. The standard diet was continued during the study (six days). Then since the third day, 120 mg of ginger extract (5 ml) divided to two doses with the brand name Aromin with 40 ml of water at every turn was given to the intervention group for four days.

In addition, the control group was given 42.5 ml of water as placebo for each turn. Prescription of ginger extract and water of both groups was performed exactly 20 minutes before gavage 9 A.M. and 6 P.M. Since probably the intervention effect would not be clear in the first two days, therefore the residual volume was recorded since the fifth and sixth days. Patients' gavage was performed in eight turns and every three hours, during the first 48 hrs of the study and the next 4 days of the study. Before each gavage turn, the gastric residual volume in patients was measured with syringe and recorded. To make the study blind, two trained nurses were used. All patients were gaviged and lavaged in 35-degree position, all patients had gastric catheter number 16, and all Patients' gavares were performed with frequently method under the gravitational influence. Cardiac and respiratory monitoring was performed during gavage and the patient was observed.

In order to assess the similarity of feeding situation, the control of serum albumin in the two groups was performed on the sixth day of the study. In order to determine the required gavage volume in 24 hours, first height and round of wrist were measured to determine the bulk and calculate the final ideal weight. Then the ideal weight was determined with Hamwi method at kilogram and according to which, required calory for preparing the gavage solution for patient was calculated. For measurements of the severity of illness indicator APACHI III was used. Blood tests required to measure APACHI III were sent. On the third day, patients were matched of confounding variant, sex and severity of disease and randomly entered the intervention and control groups. Protein filled gavage solution was prepared by using formula and under observation of a nutritionist. Each mL of the solution containing one kCal energy, for data analysis, descriptive and inferential tests was used. First, normality of data distribution was investigated with using Cromogroff Smirnoff test. According to normality of data for determining the mean residual volume difference in the two groups, independent T-test, and for the comparison in two stages before and after the test Paired T- Test was used in each group.

Ethical code:

Ethical code in research that should be observed in a clinical trial studies were observed in this study. In previous studies no known side effect has been reported in patients during use of ginger and this material is in many people's food all over the world. Pharmacognosies also declare that using this amount is authorized. Thus taking it, is without any problem ethically. The study was approved in ethical committee of the university.

Patients were permitted to be excluded whenever they would prefer to. All the information about the patients was confidential and codes were used for registration instead of names, if the patient was conscious of their own and if they weren't, an informed consent was obtained from the patient's legal guardian.

RESULTS AND DISCUSSION

Of the 30 patients included in the study, 6 patients due to presence of less than six days and weaning from the mechanical ventilation device because of improved breathing, beginning mouth feeding and a case of death due to respiratory failure were excluded. Of the 24 patients enrolled, 12 were male and 12 were female. Patients were in the range of 20-65 years old with mean and standard deviation 51.79 ± 10.8927 . According to the matching done in the first stage, it is showed that there was no significant difference among age, sex, mean of APACHI III score, required energy, also between albumin levels in the two groups on the sixth day. mean and standard deviation of residual volume in the first 48 hours of the study were estimated (126.46 ± 24.6) in the intervention group and (111.167 ± 14.14) in the control group that according to the normality of the data and the use of independent T- test the thesis of equality of the means had no significant difference. But after 48 hours of starting treatment, the average of mean and standard deviation of residual volume in the fifth and sixth days was calculated (24.58 ± 16.81) in the intervention group and (108.33 ± 15.09) in the control group that according to the independent T-test a significant difference was showed in the means of the two groups. ($P < 0.0001$) (Table No.1)

Table 1: Determining the mean residual volume in the intervention and control groups and the control of before and after the start of intervention and the difference of before and after the intervention in the two groups.

Groups	mean and standard deviation of residual volume in 48 hours before the start of intervention	mean and standard deviation of residual volume in the fifth and sixth days of the study	Difference of mean before and after the intervention	P-Value
Intervention group	126.46 ± 24.6	24.58 ± 16.81	101.87 ± 35.49	$P < 0.0001$
Control group	111.167 ± 14.14	108.33 ± 15.09	2.83 ± 24.16	N.S

In addition, for a more accurate comparison, the mean and standard deviation of the residual volume in the intervention group before and after intervention were 126.46 ± 24.6 and 24.59 ± 16.81 respectively with a difference of 101.87 ± 35.49 that this difference was significant with the use of paired T-test, but in the control group were 111.17 ± 14.14 and 108.33 ± 15.09 respectively, with a difference of 2.83 ± 24.16 that this difference was not significant with the use of paired T-test (Figure 1, 2).

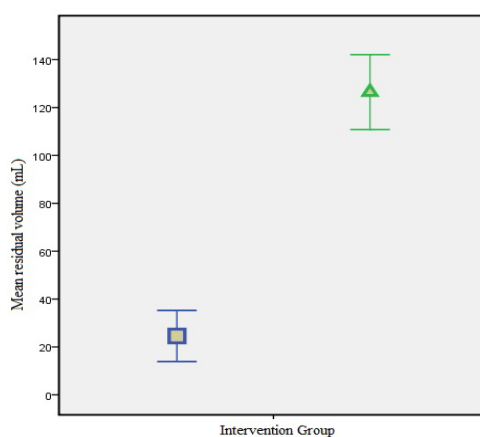


Fig. 1: Comparison of mean residual volume before and after the intervention in the intervention group
 - (small triangle in the diagram represents the residual volume in the intervention group before intervention)
 - (small square in the diagram represents the residual volume in the intervention group after intervention)

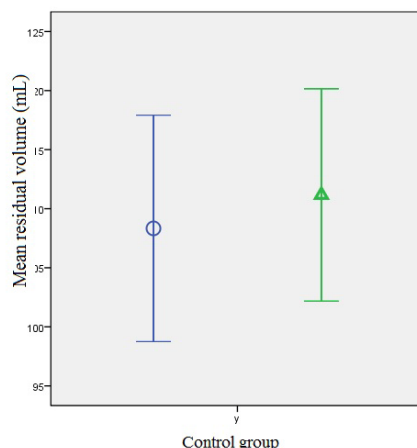


Fig. 2: Comparison of mean residual volume before and after the intervention in the control group
 - (Small triangle in the diagram represents the residual volume in the control group before the intervention)
 - (Small circle in the diagram represents the residual volume in the control group after the intervention)

Conclusion:

This study showed that ginger extract compared to placebo is effective on mean gastric residual volume, and it makes it reduce. Gastric residual volume is an incident of the rate of gastric emptying. The faster the emptying is the less the gastric residual volume will be. Hu and his colleagues' results of study show an increase in the rate of gastric emptying [15]. Kong Lee Ann Wu and colleagues' study showed that ginger increases gastric emptying in healthy people [18]. In another study performed in 1388, with the use of ginger extract in patients with Adults Respiratory Distress Syndrome under mechanical ventilation, the amount of tolerated food, and the amount of calory intake and the amount of residual food volume were measured. So, the amount of tolerated food and calory intake were more in ginger recipient group than in placebo group [19].

Measuring gastric residual volume in the present study was done in two stages before the intervention (first two days of the study) and two days after intervention (on the fifth and sixth days). Designing before and after provides two advantages for assessing results. First, the researchers were able to compare the mean residual volumes in the first 48 hours of the study in the two groups. Second, it was observed the means of the two groups were not significantly different before intervention. This type of designing before and after is the strength of this study that the difference of means, which have been compared in the two groups, was considered in it and the comparison of the intervention and control groups was performed after applying the condition. On the other hand, it was possible to compare individuals with themselves before and after the intervention in the groups receiving ginger and placebo.

Ginger is a plant which is used as a domestic treatment of digestive problems in all over the world. In recent years more researcher have paid attention to survey of ginger products and it's mechanism of function in gastrointestinal tract [16, 20]. With this purpose, Ghayur and colleagues studied about the prokinetic effect of aqueous alcoholized ginger extract in mice stomachs in a study on mice. The results of this study showed that the extract caused the prokinetic activation in mouse stomach [21]. Since the increase in prokinetic activation is related to faster gastric emptying, the results of the study are in agreement with this study. Phillips and colleagues examined the effect of 1 gr powdered ginger on gastric emptying with the use of labeled paracetamol pill on 16 volunteers. In this study, ginger showed no effect on gastric emptying. Observing is not ginger effect could have been due to small sample size or low dose of powdered ginger used in the study [22]. Based on the references, taking dose of powdered ginger is 2 to 4 grams per day [23].

In this study, the amount of patients' received calories had no significant difference in the intervention, control groups while in Shariat Panahi, and colleagues' study the amount of received calories by intervention group patients within the first 48 hours is significantly different from placebo receivers [19]. No differences could have been due to none of the study participants had residual volume greater than 200 mL and based on the latest guidelines in nutrition of patients in Intensive care units, stopping one turn of nutrition in residual volumes more than 200, and some references 400 mL, and also is according to patients' clinical symptoms [24, 25]. That the patients of this study didn't have this characteristic, thus the nutrition was on order. In the present study, the nutritional status of the two group's intervention and control was similar and the mean of albumin in the sixth day of the study in the two groups were not significantly different. In the study of Shariat Panahi and colleagues also there was no significant difference between albumin levels in the beginning and end of the study due to the same feeding condition of groups in the study [26].

In this study, the indicator APACHI III was used to match the severity of diseases of the patients under mechanical ventilation. In a study which MacLaren has performed on hospitalized patients in intensive care

units APACHI III was used to assess the severity of disease [12]. In Powers' study the severity of diseases was measured by indicator APACHI II [27, 28]. This study showed that the ginger extract can reduce gastric residual volume in patients under mechanical ventilation admitted to intensive care units. Since food intolerance and the outcome malnutrition are common in patients in intensive care units, therefore it is recommended to use this complement treatment, which in common doses in studies is without any adverse effect, to improve the gastrointestinal motility and enhance the food tolerance. By improving the nutrition process in these patients, complications caused by malnutrition due to increased gastric residual volume, and food intolerance, can be prevented. Also with decrease in gastric residual volume the risk of gastric aspiration reduces and the time of stay in intensive care units is reduced.

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